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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,345	04/06/2001	Jean-Claude Chermann	065691-0216	4575

22428 7590 08/13/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/827,345	CHERMANN ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/11/04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26- 30 is/are pending in the application.

4a) Of the above claim(s) 28 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 26,27,29 and 30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/2004 has been entered.

Election/Restrictions

Newly amended claim 28 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims under examination are drawn to antibodies and this claim is drawn to a method of detecting antibodies.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 28 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The specification does not contain sequence identifiers (SEQ ID No.) in all locations where sequences are disclosed, see at least page 15, lines 1- 17. On page 15, lines 1 and 2, it also appears that two numbers are associated with the sequence.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this Office Action will be held non-responsive.

Priority

It is noted that Applicant has filed a translation of the priority document.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

Claim 28 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The claim has been amended to an invention that was not examined and is withdrawn from consideration.

Claim Rejections - 35 USC § 101

Claims 26 and 27 are rejected under 35 U.S.C. 101 because they read on a product of nature. Human beings that contain the antibody are encompassed by the claims.

The rejection is moot in light of the amendment, the antibodies are now

"isolated".

Claim Rejections - 35 USC § 102

The rejection of claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as anticipated by Liabeuf is withdrawn.

Applicant has amended the claims to not read on the antibody cited in the rejection.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the term "cryptic epitope" on page 3, lines 21- 37 is defined.

Applicant agues the term is defined.

Applicant's argument has been fully considered and not found persuasive.

It is not stated in the claim what the cryptic epitope is. While a sequence comprising the epitope is recited, it is not clear when it is seen or when it is seen.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to any antibody that binds the recited motif.

Applicant only has shown possession of three antibodies as listed on the bottom of page 14.

It is concluded that Applicant was only in possession of those antibodies and not the whole range as claimed.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph. It appears from reading the specification that antibodies that recognize the crytic epitope of beta 2 microglobulin are required. The specification does not provide a reproducible method to make antibodies that will always have this specificity or point to any direction to obtain said antibodies. Hence, It would require an undue experimentation to enable the invention. Therefore, deposit of a reference antibody is required.

For the reasons discussed above, it is apparent that the antibodies specifically recited in the claims are required to practice the claimed invention. As a required element they must be known and readily available to the public or obtainable by repeatable method set forth in the specification, or otherwise readily available to the public. If not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposits of the antibodies. See 37 CFR 1.802.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

(a) during the pendency of this application, access to the deposits will be afforded to one determined by the commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(C) the deposits will be maintained in the public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d)a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposits will be replaced if they should become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 101

Claim 30 is rejected under 35 U.S.C. 101 because they read on a product of nature.

The antibody is not isolated and reads on an antibody as found in an individual.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Arthur *et al.* (Science 1992 Vol. 258, pages 1935- 8) in view of Galea et al. (Vaccine Vol 17, pages 1700- 1705, 1999 from IDS).

Arthur *et al.* disclose polyclonal antibodies that bind to betamicroblogulin and neutralize HIV infection.

Arthur *et al.* do not disclose the names of specific antibodies but Galea et al. refer to the antibodies as B1G6 (page page 1701 column 1, first paragraph). This is the same antibody as disclosed in the specification.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials of Arthur *et al.* that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Thus, Arthur *et al.* anticipate the claimed invention.

Claims 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Devaux *et al.* (Res. Immunology 1990, from IDS) in view of Galea et al. (Vaccine Vol 17, pages 1700- 1705, 1999 from IDS).

Devaux *et al.* disclose the names of specific antibodies, B1.1G6 and B2.62.2 but Galea et al. refer to the antibodies as B1G6 (page page 1701 column 1, first paragraph). While the antibodies do not have the same name, they appear to have the same binding characteristics. The names of the antibodies in the specification are also similar.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials of Devaux *et al.* that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Thus, Arthur et al. or Devaux et al. anticipate the claimed invention.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill
Patent Examiner
August 8, 2004

James C. Housel 8/9/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600